

What is claimed:

1. A steerable stylet for use within a lumen of an intravascular device comprising:

5 a stylet assembly having a distal end portion and a proximal end portion, said stylet assembly including:

a stylet wire having a lumen defined therein, said stylet wire having an outer diameter of less than 0.016 inches and a beam strength of at least 0.005 lbf as measured by the ASTM E855-90 3-point bend test; and

10 a core wire positioned within said lumen of said stylet wire and having a distal end portion of said core wire operably secured to said stylet wire proximate a distal end portion of said stylet wire; and

a handle proximate said proximal end portion of said stylet assembly, said handle including:

15 a hand-held housing structure operably connected to one of a proximal end portion of said stylet wire and a proximal end portion of said core wire;

an adjustable tensioner mechanism operably connected to the other of said proximal end portion of said stylet wire and said proximal end portion of said core wire to adjust a relative tension force applied between said stylet wire and said core wire; and

20 a tension limiter operably arranged to limit said tension force applied between said core wire and said stylet wire to a limit force that is less than a breaking stress force of said stylet wire when said stylet assembly is positioned within said lumen of said intravascular device.

25 2. The steerable stylet of claim 1 wherein said breaking stress force of said stylet wire is at least six pounds and said limit force of said tension limiter is less than four pounds.

3. The steerable stylet of claim 1 wherein said adjustable tensioner mechanism operably engages with a separate compressible member to increase a force opposing movement of said adjustable tensioner mechanism so as to provide tactile feedback to an operator that is generally indicative of said relative tension force.

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4. The steerable stylet of claim 1 wherein said beam strength of said stylet wire is sufficient to cause said stylet wire to return to at least an original position of said stylet wire as said relative tension force is removed from said stylet wire.

10 5. The steerable stylet of claim 1 wherein said stylet wire includes a series of at least ten notches defined along a distal region of said stylet wire.

6. The steerable stylet of claim 5 wherein said series of a least ten notches includes at least a portion of said notches having a progressively decreasing depth distally to proximally along said series.

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7. The steerable stylet of claim 6 wherein said portion of said notches having said progressively decreasing depth comprises between five percent and fifty percent of said series.

20 8. The steerable stylet of claim 6 wherein each of said notches in said portion of said notches having said progressively decreasing depth has a constant decrease in depth between adjacent notches.

9. The steerable stylet of claim 5 wherein said distal region is defined beginning between 0.050 inches and 1.000 inches proximal to said distal end of said stylet wire and includes at least twenty notches of between 0.005 inches and 0.015 inches longitudinal width with a spacing between adjacent notches of between 0.010 inches and 0.050 inches and a depth of at least ten of the most distal notches of said series being approximately equal to a radius of said stylet wire minus a wall thickness of said stylet wire.

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10. The steerable stylet of claim 5 wherein at least three of the most proximal notches of said series have a progressively decreasing depth with a constant decrease in depth between adjacent notches.

5 11. The steerable stylet of claim 1 wherein said stylet wire includes a plurality of separate sets of notches defined along a distal region of said stylet wire.

12. The steerable stylet of claim 11 wherein each set of notches is spaced apart from one another by at least 0.1 inches and each set of notches includes at least a plurality of notches  
10 having a longitudinal width of between 0.005 inches and 0.015 inches with a spacing between adjacent notches of between 0.010 inches and 0.050 inches.

13. The steerable stylet of claim 11 wherein at least one of said sets of notches includes at least a portion of said notches having a progressively decreasing depth distally to proximally  
15 along said series.

14. The steerable stylet of claim 11 wherein at least two of said sets of notches have different radial orientations of said notches such that the stylet assembly creates curves in two separate planes in response to said relative tension force.

20 15. The steerable stylet of claim 11 wherein at least two of said sets of notches have different spacings and widths of said notches such that the stylet assembly creates curves at two different times in response to said relative tension force.

25 16. The steerable stylet of claim 1 wherein said proximal end portion of said core wire is fixedly connected to said housing structure, said proximal end portion of said stylet wire is fixedly connected to said adjustable tensioner mechanism and said tension limiter has a first end portion fixedly connected to said housing structure and a second end portion operably connected to said adjustable tensioner mechanism.

17. The steerable stylet of claim 16 wherein said tension limiter is comprised of a constant force spring with a maximum tensile retention force less than the breaking stress force of said stylet wire.

5 18. The steerable stylet of claim 1 wherein said tension limiter is comprised of a spring with a maximum compressive retention force less than the breaking stress force of said stylet wire.

19. The steerable stylet of claim 1 wherein said tension limiter is comprised of an elastomer with a maximum compressive retention force less than the breaking stress force of said stylet wire.

10 20. The steerable stylet of claim 1 wherein said distal end portion of said core wire is operably secured to said distal end portion of said stylet wire without annealing either of said distal end portions.

15 21. A steerable stylet for use within a lumen of an intravascular device comprising:

20 a stylet wire having a distal end portion, a proximal end portion and a lumen defined in said stylet wire, said stylet wire having an outer diameter of less than 0.016 inches and a beam strength of at least 0.005 lbf as measured by the ASTM E855-90 3-point bend test;

a core wire having a distal end portion and a proximal end portion, said core wire positioned within said lumen of said stylet wire and having said distal end portion of said core wire operably secured to said stylet wire proximate said distal end portion of said stylet wire; and

25 a handle proximate said proximal end portion of said stylet wire, said handle including a hand-held housing structure having:

means for adjusting a relative tension force applied between said stylet wire and said core wire; and

means for limiting said relative tension force to a limit force that is less than a breaking stress force of said stylet wire when said stylet wire is positioned within said lumen of said intravascular device.

5 22. The steerable stylet of claim 21 wherein said breaking stress force of said stylet wire is at least six pounds and said limit force of said tension limiter is less than four pounds.

23. The steerable stylet of claim 21 wherein said handle further includes means for providing tactile psuedo-feedback to an operator that is generally indicative of said relative tension force.

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24. The steerable stylet of claim 21 wherein said beam strength of said stylet wire is sufficient to cause said stylet wire to return to at least an original position of said stylet wire as said relative tension force is removed from said stylet wire.

15 25. The steerable stylet of claim 21 wherein said stylet wire includes at least one means for altering a wall strength of said stylet wire along a distal region of said stylet wire.

26. The steerable stylet of claim 25 wherein said means for altering the wall strength creates a radially differential wall strength between generally opposing walls of said stylet wire.

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27. The steerable stylet of claim 25 wherein said means for altering the wall strength is selected from the set consisting of: means for removing material at a series of locations along said stylet wire, means for adding material at a series of locations along said stylet wire, or any combination thereof.

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28. The steerable stylet of claim 25 wherein said means for altering the wall strength comprises a series of means for altering a material characteristic of a wall of said stylet wire located along a portion of said stylet wire.

29. The steerable stylet of claim 28 wherein each of said means for altering a material characteristic of said wall in said portion have differing characteristics between adjacent means.

30. The steerable stylet of claim 28 comprising a plurality of said means for altering the wall strength, each said means for altering the wall strength being spaced apart from one another by at least 0.1 inches.

31. The steerable stylet of claim 30 wherein at least two of said means for altering the wall strength have different radial orientations of said series of means for altering the material characteristic such that the stylet assembly creates curves in two separate planes in response to said relative tension force.

32. The steerable stylet of claim 30 wherein at least two of said series of means for altering the material characteristic have different spacings and widths such that the stylet assembly creates curves at two different times in response to said relative tension force.

33. The steerable stylet of claim 21 wherein said distal end portion of said core wire is operably secured to said distal end portion of said stylet wire by means for adhering without annealing either of said distal end portions.

34. A method of steering a stylet within a lumen of an intravascular device comprising:  
providing a steerable stylet including:

a stylet assembly having a distal end portion and a proximal end portion,  
said stylet assembly including a stylet wire having a lumen defined therein, said  
stylet wire having an outer diameter of less than 0.016 inches and a beam strength  
of at least 0.005 lbf as measured by the ASTM E855-90 3-point bend test, and a  
core wire positioned within said lumen of said stylet wire and having a distal end  
portion of said core wire operably secured to said stylet wire proximate a distal  
end portion of said stylet wire; and

a handle operably connected to said stylet wire proximate said proximal end portion of said stylet assembly, said handle including a hand-held housing structure, a tension adjuster and a tension limiter;  
inserting at least a portion of said stylet assembly into said lumen of said

5 intravascular device; and

selectively deflecting a distal end portion of said intravascular device by using said tension adjuster to adjust a relative tension force applied between said stylet wire and said core wire in such a manner that said tension limiter limits said relative tension force to a limit force that is less than a breaking stress force of said stylet wire.

10 35. The method of claim 34 wherein the step of selectively deflecting deflects said distal end portion of said intravascular device to a maximum deflection of at least 180 degrees from an original position of said distal end portion of said intravascular device at a bend radius of less than an inch.

15 36. The method of claim 34 wherein the step of selectively deflecting deflects said distal end portion of said intravascular device to a maximum deflection of at least 45 degrees from an original position of said distal end portion of said intravascular device at a bend radius of less than an inch.

20 37. The method of claim 34 further comprising:

returning said distal end portion of said intravascular device to at least an original position of said distal end portion of said intravascular device by releasing said relative tension force applied between said stylet wire and said core wire and using said beam  
25 strength of said stylet wire to cause said stylet wire to return to a position beyond an original position of said stylet wire.

38. The method of claim 34 wherein said step of selectively deflecting is repeated at least fifty times without inducing stress or fatigue failure in said stylet wire.

39. The method of claim 34 wherein said stylet assembly includes a plurality of regions along said distal end portion having differing wall strengths such that the step of selectively deflecting creates a compound curve of said distal end portion.

5 40. The method of claim 39 wherein at least two of said plurality of regions are radially offset with respect to each other and the step of selectively deflecting creates curves in at least two different planes.

41. The method of claim 39 where at least two of said plurality of regions having differing  
10 characteristics and the step of selectively deflecting creates curves at two different times.

42. A steerable stylet for use within a lumen of an intravascular device comprising:  
a stylet assembly having a distal end portion and a proximal end portion, said  
stylet assembly including:

15 a stylet wire having a lumen defined therein, said stylet wire having an outer diameter of less than 0.016 inches and a beam strength of at least 0.005 lbf as measured by the ASTM E855-90 3-point bend test, said stylet wire includes a series of at least ten notches defined along at least one distal region of said stylet wire; and

20 a core wire positioned within said lumen of said stylet wire and having a distal end portion of said core wire operably secured to said stylet wire proximate a distal end portion of said stylet wire; and

a handle proximate said proximal end portion of said stylet assembly, said handle  
including a hand-held housing structure having means for adjusting a relative tension  
25 force applied between said stylet wire and said core wire.

43. The steerable stylet of claim 42 wherein said series of a least ten notches includes at least a portion of said notches having a progressively decreasing depth distally to proximally along said series.

44. The steerable stylet of claim 43 wherein said portion of said notches having said progressively decreasing depth comprises between five percent and fifty percent of said series.

45. The steerable stylet of claim 43 wherein each of said notches in said portion of said notches having said progressively decreasing depth has a constant decrease in depth between adjacent notches.

46. The steerable stylet of claim 42 wherein said distal region is defined beginning between 0.050 inches and 1.000 inches proximal to said distal end of said stylet wire and includes at least twenty-five notches of between 0.005 inches and 0.015 inches longitudinal width with a spacing between adjacent notches of between 0.010 inches and 0.050 inches and a depth of at least ten of the most distal notches of said series being approximately equal to a radius of said stylet wire minus a wall thickness of said stylet wire.

47. The steerable stylet of claim 42 wherein at least three of the most proximal notches of said series have a progressively decreasing depth with a constant decrease in depth between adjacent notches.

48. The steerable stylet of claim 42 wherein said stylet wire includes a plurality of separate sets of notches defined along a distal region of said stylet wire.

49. The steerable stylet of claim 48 wherein each set of notches is spaced apart from one another by at least 0.1 inches and each set of notches includes at least a plurality of notches having a longitudinal width of between 0.005 inches and 0.015 inches with a spacing between adjacent notches of between 0.010 inches and 0.050 inches.

50. The steerable stylet of claim 48 wherein at least one of said sets of notches includes at least a portion of said notches having a progressively decreasing depth distally to proximally along said series.

51. The steerable stylet of claim 48 wherein at least two of said sets of notches have different radial orientations of said notches such that the stylet assembly creates curves in two separate planes in response to said relative tension force.

5 52. The steerable stylet of claim 48 wherein at least two of said sets of notches have different spacings and widths of said notches such that the stylet assembly creates curves at two different times in response to said relative tension force.

53. The steerable stylet of claim 42 wherein said distal end portion of said core wire is  
10 operably secured to said distal end portion of said stylet wire without annealing either of said distal end portions.

54. A steerable stylet for use within a lumen of an intravascular device comprising:  
a stylet assembly having a distal end portion and a proximal end portion, said  
15 stylet assembly including:

a stylet wire having a lumen defined therein, said stylet wire having an  
outer diameter of less than 0.016 inches and a beam strength of at least 0.005 lbf as  
measured by the ASTM E855-90 3-point bend test, said stylet wire includes a  
series of means for altering a material characteristic of a wall of said stylet wire  
20 located along a portion of said stylet wire; and

a core wire positioned within said lumen of said stylet wire and having a  
distal end portion of said core wire operably secured to said stylet wire proximate a  
distal end portion of said stylet wire; and

a handle proximate said proximal end portion of said stylet assembly, said handle  
25 including a hand-held housing structure having means for adjusting a relative tension  
force applied between said stylet wire and said core wire.

55. The steerable stylet of claim 54 wherein each of said means for altering a material  
characteristic of said wall in said portion have differing characteristics between adjacent means.

56. The steerable stylet of claim 54 comprising a plurality of said series of means, each of said series of means being spaced apart from one another by at least 0.1 inches.

57. The steerable stylet of claim 56 wherein at least two of said series of means have different radial orientations such that the stylet assembly creates curves in two separate planes in response to said relative tension force.

58. The steerable stylet of claim 56 wherein at least two of said series of means have different characteristics such that the stylet assembly creates curves at two different times in response to said relative tension force.

59. The steerable stylet of claim 54 wherein said distal end portion of said core wire is operably secured to said distal end portion of said stylet wire by means for adhering without annealing either of said distal end portions.